

### Remarks

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

Thus, claim 1 has been amended to clarify the invention by incorporating language along the lines set forth in the second full paragraph on page 6 of the specification, as will be discussed below.

Amended claim 1 refers to “a total concentration of proton-sources” instead of “a total proton concentration” in consideration of the calculation of this parameter, for example, at page 24, lines 15-19 of the specification, where the amount of added water (instead of the amount of protons formed by dissociation of water) is used for the calculation.

Claims 4, 5, 7, 9, 10 and 12 have been amended to be consistent with the language employed in amended claim 1.

Claim 8 has been amended in response to the rejection of this claim under the second paragraph of 35 U.S.C. §112, which is now considered moot.

The patentability of the presently claimed invention over the disclosures of the references relied upon by the Examiner in rejecting the claims will be apparent upon consideration of the following remarks.

Thus, the rejection of claims 1, 2, 4-8 and 9 under 35 U.S.C. §102(b) as being anticipated by EP 1 048 683 (EP ‘683) is respectfully traversed.

Applicants note that after setting forth this rejection on page 2 of the Office Action, the Examiner discusses EP ‘683, and then on page 4 the Examiner turns to EP 0 299 730 (EP ‘730), although a rejection based on EP ‘730 is not specifically set forth by the Examiner. For purposes of the following discussion, Applicants assume that the Examiner meant to specifically set forth a rejection based on EP ‘730.

The present invention, as clarified in amended claim 1, is directed to a process for producing an aliphatic polyester of **a controlled molecular weight** by ring-opening polymerization of a cyclic polyester containing **water in excess of 80 ppm while controlling a total concentration of proton-sources including water and proton-source impurities** in the cyclic ester so as to provide a desired weight-average molecular weight of resultant **aliphatic polyester by varying the content of the water in the cyclic ester**, and compounding the resultant aliphatic polyester with a carboxyl group-capping agent. The positive use of water

at a large level negated heretofore for molecular weight control of the resultant aliphatic polyester and obviation of adverse effects thereof by compounding of the resultant polyester with a carboxyl group-capping agent, are the principal characteristic of the present invention. For accurate molecular weight control, the contribution of proton-source impurities, such as glycolide acid (GA) and glycolic acid dimer (GA2), is also taken into account as described at page 23 of the specification.

Such a characteristic concept or feature of the present invention is not taught or suggested by the EP '683 or EP '730 reference.

EP '683, at paragraph [0406], prefers a monomer having a moisture content of not more than 80 ppm and an acid value of not more than 0.12 mgKOH/g. These levels are substantially lower than those adopted in the Examples of the present application. In Polymer Synthesis Example 1 described at pages 31– 32 of the specification (for production of PGA sample A used in Examples 1– 4 described at page 34), the added water amount of 3.85g already amounts to 170 ppm ( $=3.85/22500 \times 10^6$  as shown in the calculation example described at page 24) of the monomer. The impurity contents of 50 ppm of glycolide acid (GA) and 360 ppm of glycolic acid dimer (GA2) correspond to an acid value of ca. 0.21mgKOH/g in view of the molecular weights of 76 for GA, 134 for GA2 and 58 for KOH as shown by the following calculation:

$$58 \times 1000 \times (50/56 + 360/134) = \text{ca. } 0.21.$$

Including the contribution of these proton sources, the total proton(-source) concentration for Polymer Synthesis Example 1 amounts to 0.180 mol% and resulted in PGA Sample A having a weight-average molecular weight (Mw) of 193000 as represented by the leftmost triangular mark shown in Fig.1 of the present application.

The possibility of such an accurate molecular weight control by using a monomer containing high levels of water and proton-source impurities, as demonstrated in Fig. 1, is not taught or suggested by either EP '683 or EP '730.

The Examiner refers to paragraph [0468] of EP '683 (using mixture of a caprolactone monomer containing 150 ppm of water and a lactide monomer containing 50 ppm of water) which is, however, a Comparative Example of which the value is negated by EP '683 *per se*. The number-average molecular weight of the polymer obtained in the Comparative Example is simply referred to as 76,400. No contribution of the water or acid value to the molecular weight control is suggested by EP '683.

The rejection of claim 2 under 35 U.S.C. §103(a) as being unpatentable over EP '683 or EP '730 in view of USP 5,885,709 (US '709) or USP 2,937,164 (US '164), as well as the rejection of claim 3 under 35 U.S.C. §103(a) as being unpatentable over EP '683 or EP '730 in view of JP 57-094019 (JP '019) are respectfully traversed.

The comments set forth above concerning the EP '683 and EP '730 references are equally applicable to these rejections.

None of the US '709, US '164 or JP '019 references cure the defect of the EP '683 and EP '730 references in failing to suggest the subject matter of amended claim 1 as set forth above. Therefore, since claims 2 and 3 are dependent on claim 1, the secondary references also fail to suggest the subject matter of these claims.

Thus, the present invention, based on the discovery of a total proton-source concentration including a high level of water as an effective index for molecular weight control, is not anticipated by or obvious over any of the cited references, alone or in the combination.

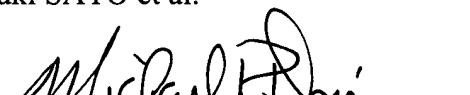
The Examiner has provisionally rejected claims 1-12 for obviousness-type double patenting based on the claims of Serial No. 10/577,379. The Examiner is kindly requested to hold this rejection in abeyance, pending an indication that the claims of the present application are otherwise in condition for allowance.

Therefore, in view of the foregoing amendments and remarks, it is submitted that each of the grounds of rejection set forth by the Examiner has been overcome, and that the application is in condition for allowance. Such allowance is solicited.

Respectfully submitted,

Hiroyuki SATO et al.

By:



Michael R. Davis

Registration No. 25,134

Attorney for Applicants

MRD/pth  
Washington, D.C. 20006-1021  
Telephone (202) 721-8200  
Facsimile (202) 721-8250  
September 3, 2008